

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

PAMELA BUTLER,)	
)	
Plaintiff,)	
)	
vs.)	Case No. 4:18-cv-01701-AGF
)	
MALLINCKRODT LLC, et al.,)	Lead Case
)	
Defendants.)	

MEMORANDUM AND ORDER

Plaintiffs Pamela Butler, Kenneth Koterba, Anthony Hines, and Emery David Walick, III assert public liability actions under the Price-Anderson Act (PAA) as amended, 42 U.S.C. §§ 2014, 2210. They allege that they developed cancer after being exposed to excessive radiation releases from improper handling of radioactive waste materials by Defendants Mallinckrodt LLC and Cotter Corporation at various times over the past half century. After filing suit, Plaintiffs' cases were consolidated before the undersigned for pretrial purposes only.

The matters are now before the Court on Defendants' joint¹ motions to exclude the testimony of three of Plaintiffs' experts: James Wells, Ph.D., James Clark, Ph.D., and Howard Hu, M.D. ECF Nos. 47, 49 & 51.² The Court heard oral argument on these motions on March 10, 2022. For the reasons set forth below, the Court will grant in part

¹ In addition to joining Mallinckrodt's motions, Cotter has submitted supplemental memoranda in support of the motion to exclude the testimony of James Wells. See ECF Nos. 54 & 84.

² Unless otherwise indicated, all citations to documents in the record refer to documents filed in the lead case, No. 4:18-cv-01701-AGF

and deny in part Defendants' motions to exclude Wells and Hu; and the Court will grant in full Defendants' motion to exclude Clark.

BACKGROUND

During World War II, Mallinckrodt contracted with the federal government to produce radioactive material for the Manhattan Project. In connection with this project, radioactive waste materials were stored in downtown St. Louis and at a storage site north of the St. Louis Airport known as "SLAPS." The federal government's Manhattan Engineer District (MED) acquired SLAPS in 1946.

The MED, and its successor, the Atomic Energy Commission (AEC), operated and stored radioactive waste product at SLAPS from 1946 until July 1953. The radioactive waste product stored at SLAPS included K-65, a radium-bearing residue that produced radon. However, it is undisputed that the AEC removed the K-65 from SLAPS by the end of 1949.

The AEC contracted with Mallinckrodt to operate SLAPS beginning in July of 1953 and continuing until February 14, 1966. Throughout the 1950s, the AEC and Mallinckrodt began removing radioactive waste from SLAPS, but a substantial volume of waste material remained at SLAPS until it was transferred to an interim storage site in Hazelwood, Missouri, known as "Latty Avenue" or "HISS."

Between 1969 and 1973, Cotter possessed and managed the radioactive waste at Latty Avenue. SLAPS, Latty Avenue, and other properties adjacent to Coldwater Creek—a creek that flowed near both sites—were included as part of the U.S. Army

Corps of Engineers' Formerly Utilized Sites Remedial Action Program (FUSRAP), an environmental remediation program addressing radiological contamination.

Plaintiffs lived or worked near these sites for many years dating back to the 1960s, and each was subsequently diagnosed with cancer. Specifically, Butler lived near the sites from approximately 1983 to 1993 and thereafter continued to attend church and engage in outdoor recreational activities in and around SLAPS, Latty Avenue, and Coldwater Creek. She was diagnosed with breast cancer in 2016, at the age of 56. *See* ECF No. 1, Butler Comp. at ¶ 24; *see also* ECF No. 52-4, Defs.' Ex. A4, Hu Report as to Butler.

Koterba has lived near the sites since 1964. As a child, he would frequently fish and play in Coldwater Creek, as well as engage in outdoor recreational activities in and around the creek, SLAPS, and Latty Avenue. He was diagnosed with an intra-axial brainstem tumor in 2015, at the age of 58. *See* Case No. 4:18-cv-01702-AGF, ECF No. 1, Koterba Comp. at ¶ 24; *see also* ECF No. 52-3, Defs.' Ex. A3, Hu Report as to Koterba.

Hines lived near the sites from 1962 to 1974, and from 1976 to 1982. While living near the sites as a child, he would often play in Coldwater Creek near Latty Avenue, as well as engage in outdoor recreational activities in and around the creek, SLAPS, and Latty Avenue. He was diagnosed with mantle cell lymphoma in 2015, at the age of 52. *See* Case No. 4:18-cv-01703-AGF, ECF No. 1, Hines Comp. at ¶ 24; *see also* ECF No. 52-1, Defs.' Ex. A1, Hu Report as to Hines.

Walick lived near the sites from approximately 1990 to 1997, 2008 to 2010, and 2012 to 2014. As a child, he would play in Coldwater Creek near SLAPS, as well as engage in outdoor recreational activities in and around the creek, SLAPS, and Latty Avenue. He was diagnosed with medulloblastoma, a type of brain tumor, in 2014, at the age of 23. *See* Case No. 4:18-cv-01704-AGF, ECF No. 1, Walick Comp. at ¶ 24.

Plaintiffs' Lawsuit Under the PAA

As noted above, each Plaintiff has asserted a public liability action under the PAA. The PAA creates federal jurisdiction for “any public liability action arising out of or resulting from a nuclear incident” in the district court located in the district where the incident occurred. 42 U.S.C. § 2210(n)(2); *see also In re Cotter Corp., (N.S.L.)*, 22 F.4th 788, 793 (8th Cir. 2022). The “public-liability provision [creates] a federal cause of action for injuries caused by nuclear exposure.” *Halbrook v. Mallinckrodt, LLC*, 888 F.3d 971, 974 (8th Cir. 2018). This provision incorporates substantive state-law standards for liability “unless such law is inconsistent with the provisions of [the PAA].” 42 U.S.C. § 2014(hh).

In accordance with the PAA and Missouri substantive law, Plaintiffs must prove a causal link between their exposures to radiation and their cancers. The difficulty in proving such causation has been the subject of litigation in other federal courts, including *In re TMI Litigation*, 193 F.3d 613 (3d Cir. 1999), arising out of the Three Mile Island nuclear power plant accident, and *McMunn v. Babcock & Wilcox Power Generation Grp., Inc.*, 869 F.3d 246 (3d Cir. 2017), a public liability action that, like the instant one, alleged cancer due to radiation released by a nuclear facility dating back

to the 1960s.

As these courts explained:

[I]t is impossible to determine with certainty that radiation is the cause of a given incidence of cancer for three reasons. First, numerous factors other than radiation may cause cancer. That is, “a given percentage of a defined population will contract cancer even absent any exposure to ionizing radiation. Second, there is no clear difference between cancers caused by radiation or by other factors. No characteristic of a given cancer (such as its type or severity) are known to suggest that “manmade” radiation or even any radiation was the cancer's cause. Third, because the relevant changes occur on the cellular level, they are not detected or detectable at the time they occur. It can take many years—seemingly a variable number of years—between an exposure to radiation and the “possible detection of a resulting cancer.”

McMunn, 869 F.3d at 255 (citing *TMI Litig.*, 193 F.3d at 643–44).

Further, “[u]nlike with PCBs, asbestos or tobacco byproducts, we are constantly exposed to radiation on a daily basis. We are exposed from numerous natural sources including the sun, or naturally occurring radioactive elements such as radon in the ground surrounding our homes.” *Id.* at 277 (McKee, J., concurring).

In order to help prove causation and other elements of their personal injury claims in this case, Plaintiffs have proffered the three experts that are the subject of Defendants’ motions.³

³ Plaintiffs disclosed their expert reports relatively early in litigation, pursuant to a Case Management Order (CMO No. 14) entered when these cases were consolidated with a larger set of related cases, *McClurg et al. v. Mallinckrodt, LLC, et al.*, 4:12-CV-00361-AGF. *See* ECF No. 63-9 (CMO No. 14 from *McClurg*). That CMO required early disclosure of plaintiff-specific fact questionnaires, medical records, and expert disclosures on certain issues common to the litigants in this mass tort action. *See id.* It also provided procedures for failure to comply, including requiring that Defendants provide notice and an opportunity to cure deficiencies before seeking relief from the Court for noncompliance. *See id.* at 11. Plaintiffs now appear to argue that Defendants were required to comply with the notice-and-cure procedures with respect to their current

James Wells

Wells is a professional geologist with extensive experience in environmental geology, including investigating and evaluating remediation strategies for contamination in soil, air, and groundwater. Plaintiffs retained Wells to provide expert opinion testimony concerning the nature and extent of contamination on and around the SLAPS and Latty Avenue sites, as well as properties in the vicinity of these sites, including Coldwater Creek. Wells also focused on “determining the concentrations of effluent discharges at the boundary of the SLAPS and Latty Avenue sites allegedly attributable to Mallinckrodt’s and/or Cotter’s operations and whether such concentrations exceed the effluent limitations found in applicable historical federal regulations.” ECF No. 48-1, Wells Rep. at 3.

To arrive at his opinions, Wells reviewed discovery produced by the Defendants in this case as well as reports and documents made available by the U.S. Army Corps of Engineers, the AEC, and the Nuclear Regulatory Commission (NRC).

Wells opined that the SLAPS and Latty Avenue sites were contaminated with radiological materials and metals; that contamination existed even after waste was removed beginning in 1949; and that, because much of the on-site radioactive material was stored in open waste piles, contamination escaped from the SLAPS and Latty

Daubert arguments or risk waiving such arguments. See ECF No. 69 at 14 n.3. Nothing in CMO No. 14 or the current CMO in this case supports Plaintiffs’ argument. The notice-and-cure procedures in CMO No. 14 relate to failures to comply with the CMO’s early disclosure requirements, not to *Daubert* arguments challenging particular expert opinions. A separate deadline was set for such *Daubert* motions, and Defendants have timely complied with that deadline.

Avenue sites and impacted neighboring properties by a number of migration pathways. Further, Wells opined that past offsite effluent concentrations in air, water, and sediment at the boundaries of SLAPS and Latty Avenue could be estimated using existing data and modeling. *See id.* at 3-4.

Wells then set forth his calculations of past offsite effluent concentrations at the boundaries of the two sites and compared these totals to the federal effluent limitations originally published in 10 C.F.R. § 20.106(a) in the year 1960. Wells explained that the federal limitations in 1960 included different limits for “soluble” and “insoluble” forms of each radionuclide, but that the regulations did not define those terms. *Id.* at 12. Wells then explained his reasons for determining that the “soluble” effluent limitations were applicable here.

Next, Wells opined that the 1960 federal “effluent limitations for water may not have been exceeded but effluent limitations for air were exceeded at both SLAPS and Latty Avenue.” *Id.* With respect to the federal effluent limitations for air, Wells specifically concluded that concentrations of radon-222 and thorium-230 at the boundary of both SLAPS and Latty Avenue in the years that Mallinckrodt and Cotter stored or handled materials at these sites exceeded the federal limitations for such radionuclides found in 10 C.F.R. § 20.106 (1960). Wells noted that “[a]fter the wastes had been removed, measured radon concentrations were much lower at both sites and concentrations likely declined even further after completion of FUSRAP soil remediation.” *Id.* at 15.

Finally, Wells allocated responsibility for this contamination between Mallinckrodt and Cotter by using six factors known in the field of environmental geology as the “Gore factors.”

In a supplemental report disclosed on August 1, 2019, Wells opined that Cotter committed multiple violations of St. Louis County Health Department regulations related to hazardous materials management, which resulted in effluent limitations being exceeded at the Latty Avenue site as discussed in Wells’s original report. Wells further opined that both Defendants’ possession, use, and/or transfer of wastes at SLAPS and Latty Avenue caused excessive radiation, in violation of the limitations set forth in 10 C.F.R. § 20, to be released in the form of contaminated sediments into Coldwater Creek and tributary ditches. *See generally* ECF No. 48-5, Defs.’ Ex. E, Wells Supp. Report.

The opinions regarding Defendants’ releases in excess of federal limits and the allocation of responsibility between the two Defendants are the focus of the current motion to exclude Wells’s testimony.

I. Releases from SLAPS

a. Radon-222 Releases from SLAPS

To arrive at his conclusion that the concentration of radon-222 at the boundary of SLAPS exceeded federal limits, Wells relied on an AEC report titled “Radon Samples Taken in Airport Area,” and dated March 29, 1948. *See* ECF No. 48-7, Defs.’ Ex. G. The report stated that “[a] survey was made at the airport area in order to determine the concentrations of radon in air, the source of this contamination being the K-65 in and around the storage shed.” *Id.* Based on the report, Wells concluded that radon

concentrations at or near the fence line of the SLAPS site were measured at levels up to 210 picocuries per liter (pCi/L)⁴ in 1948. Wells concluded that the appropriate effluent limitation for radon-222 in air under the 1960 federal regulation was 3.0 pCi/L. Thus, Wells concluded that the concentration of radon at the boundary of SLAPS as measured in the 1948 AEC report was up to 70 times higher than the federal limit. *See* ECF No. 48-1, Wells Rep. at 14.

Wells conceded that Mallinckrodt did not begin operating SLAPS until 1953 and that “material was progressively removed from [SLAPS] starting in the 1950s.” *Id.* at 12, 14. Moreover, as noted above, it is undisputed that the AEC removed the K-65—the cited source of contamination in the 1948 AEC report—by the end of 1949. *See* ECF No. 48-8, Defs.’ Ex. H. However, Wells stated that “a large volume of waste remained at SLAPS until it was transferred to [Latty Avenue] in 1966,” and “[f]or this reason, [Wells] believe[d] the 1948 radon measurements are broadly representative of emissions from SLAPS through 1966.” ECF No. 48-1, Wells Rep. at 14.

b. Thorium-230 Releases from SLAPS

To arrive at his conclusion that the concentration of thorium-230 at the boundary of SLAPS exceeded federal limits, Wells relied on measurements collected around SLAPS in 1960 and reported as part of Mallinckrodt’s internal annual monitoring program at the time. *See id.* at 16; *see also* ECF No. 48-10, Defs.’ Ex. J (Mallinckrodt

⁴ “Radioactivity is measured in picocuries. A picocurie is a unit of radioactivity equal to one-trillionth of a curie and represents 2.22 radioactive disintegrations per minute.” *Amoco Oil Co. v. Borden, Inc.*, 889 F.2d 664, 671 n.13 (5th Cir. 1989), *as clarified on denial of reh’g* (Jan. 23, 1990).

Environmental Monitoring Report, 1960). The report details 12 air samples taken from four areas around SLAPS: six samples collected north of the site, two samples from west of the site, two samples from east of the site, and two samples from south of the site. ECF No. 48-10, Defs.’ Ex. J at 11 (Annual Off-site Environmental Monitoring Report for Airport Storage Site). The report states that the sampling frequency was semiannual, and lists the “low,” “high,” and “average” measurements of uranium concentration from each of the four areas from which samples were taken. *Id.*

Despite the report’s reference to 12 samples, Wells’s report stated that “[f]our samples were collected near the SLAPS property line[.]” ECF No. 48-1, Wells Rep. at 16. Wells then pointed to the “highest concentration of uranium detected,” which was the “high” concentration for the “north of site” samples, and which was reported as “4.5 x 10-14 uc/cc.” *Compare id.*, with ECF No. 48-10, Defs.’ Ex. J at 11. Next, Wells used a table created by Mallinckrodt’s expert, Risk Assessment Corporation (RAC), showing the activity fractions of radionuclides in the air to estimate the amount each radionuclide contributed to the total 1960 measurement. ECF No. 48-1, Wells Rep. at 16.

Wells opined that these estimates were “one reliable example of air concentrations at the fence line of the SLAPS site during the period of time that waste piles were present.” *Id.* Wells then specifically opined that his estimate of “thorium-230 exceed[ed] its [federal] 10 CFR effluent limitation for air.” *Id.*

Wells further noted that his estimates may in fact have underrepresented the “maximum air concentrations historically released from the SLAPS site.” *Id.* Wells stated that “[t]ypically, modeling studies develop daily average concentrations, which are

valid across an entire year, but are not accurate for windy days. However, it is important to remember that most days, winds are mild and will have very little dust generation.”

Id. at 17. Wells concluded that “sampling conducted on a calm day, would greatly underestimate ‘average’ airborne concentrations,” and that on windy days, concentrations would likely far exceed the estimates. *Id.*

II. Releases from Latty Avenue

a. Radon-222 Releases from Latty Avenue

With respect to Latty Avenue, Wells calculated radon concentrations at the fence line by using the formula $DF = \chi/Q$. In this formula, DF = Dispersion Factor; χ = Concentration in air at a given point; and Q = release rate. Wells relied on a report by Mallinckrodt’s expert, RAC, to arrive at the values for each figure in the formula. Specifically, RAC reported a release rate of 1.2×10^{-4} Ci/s for Latty Avenue; a perimeter dispersion factor of 6.21×10^{-5} s/m³; and an average on-site radon concentration of 168 pCi/L measured at the SLAPS, as opposed to Latty Avenue, site. *See id.* at 14; *see also* ECF No. 71, Pls.’ Resp., at 9.

Using these values, Wells calculated the radon concentration at the fence line at Latty Avenue to be 7.45 pCi/L. ECF No. 48-1, Wells Rep. at 14-15. Wells then opined that this concentration was “valid for the [entire] period of time that the waste material was stored at this site” and that the concentration exceeded the 3.0 pCi/L federal limitation for radon in air. ECF No. 48-1, Wells Rep. at 15.

Cotter’s expert (who has not been challenged by Plaintiffs) asserts—and Plaintiffs do not dispute—that Wells used RAC’s radon measurements for SLAPS as a proxy for

Latty Avenue, notwithstanding that the SLAPS numbers were expressly measurements of “[r]adon [e]missions from K-65 [d]rums.” *See* ECF No. 54-1, Cotter’s Ex. A at 28.

Plaintiffs also do not dispute that K-65 was never stored at Latty Avenue. *See* ECF No. 71 at 14 (conceding that the K-65 was not moved to Latty Avenue).

b. Thorium-230 and Other Radionuclide Releases from Latty Avenue

In addition to the above-noted radon releases, Wells concluded that radioactive material was released into the air around Latty Avenue as a result of a waste drying operation, including the use of a powerful blower. Again, Wells relied on calculations performed by Mallinckrodt’s expert, RAC, of such releases for each of the six quarters between 1968 and 1971 when drying was being conducted at Latty Avenue, and of the “total curies released from each radionuclide of concern over the entirety of the drying operation.” *Id.* at 17. Wells opined that although “there is considerable uncertainty in these [RAC] calculations, they are reasonable estimates of releases to air during drying operations.” *Id.*

Wells converted the RAC calculations of releases to concentrations “by dividing by the total amount of air passing across the site each quarter.” *Id.* He opined that the result produced by this conversion was “equivalent to the average concentrations at the fence line per quarter.” *Id.* at 18. Wells then specifically opined that the thorium-230 concentration “exceed[ed] the 10 CFR effluent guideline for air in each quarter and proactinium-231 exceed[ed] the effluent guideline for two quarters in 1968.” *Id.*

Wells found this conclusion “unsurprising,” noting that the AEC issued the Latty Avenue site notices of non-compliance with federal limitations for contamination in

unrestricted areas in 1966 and 1967.⁵ For example, Wells noted that the AEC's 1966 notice identified five items of non-compliance, including finding that "contrary to 10 CFR 20.105, on May 16, 1966, radiation levels existed in the unrestricted areas around the 'Barrel storage area' such that an individual could receive a dose in excess of those limits specified in this part." *Id.* at 18. Further, in the 1967 notice, the AEC reported that "radiation levels were found emitting from the stockpile area in excess of 1.3 mr/hr at 1 meter from the ground and from the barrel storage area at 10 mr/hr at 18 inches from the barrels. Therefore, contrary to 10 CFR 20.105(b)(2), radiation levels exist in the stockpile area and unrestricted area, such that an individual continuously present in this area could receive a dose in excess of 100 millirem in any seven days." *Id.* (citing AEC, Inspection Sheet for January 11, 1967 Inspection).

III. Allocation

Wells opined that, for the period of time before wastes were transported to Latty Avenue, from 1946 to 1966, SLAPS was responsible for 100% of releases to the environment. Wells opined that, after wastes had been removed from SLAPS and transported to Latty Avenue in 1966, the Latty Avenue site was primarily responsible for the releases to communities surrounding that site. Wells concluded that properties immediately adjacent to each site were impacted dominantly by that site. Wells thus allocated release percentages between SLAPS and Latty Avenue for three time periods (pre-1966, 1966-1973, and post-1973) and for four different geographical locations: the

⁵ The record does not disclose any such notice of non-compliance issued by AEC with respect to the SLAPS site.

ballfields immediately north of SLAPS; the Latty Avenue Railroad; the Latty Avenue Vicinity Sites; and Coldwater Creek, which flowed near both sites.

Wells summarized his allocation as follows:

	Pre-1966		1966-1973		Post-1973	
	SLAPS	LATTY	SLAPS	LATTY	SLAPS	LATTY
Ballfields	100%	0%	90%	10%	90%	10%
Latty Ave. Railroad	100%	0%	10%	90%	10%	90%
Latty Ave. Vicinity Sites	100%	0%	10%	90%	10%	90%
Coldwater Creek	100%	0%	73%	27%	73%	27%

Id. at 22.

Wells noted that Coldwater Creek flowed near both properties, and he opined that “some of the wastes released in any one year are incorporated into streambed and floodplain sediments, thus are stored indefinitely in the stream system.” *Id.* at 20–21.

Wells thus relied on the “Gore Factors” to arrive at a reasonable allocation for Coldwater Creek. According to Wells, the following Gore Factors are “widely used parameters for allocating liability at [U.S. Environmental Protection Agency] Superfund sites and other cases involving toxic releases”:

- (1) the ability of the parties to demonstrate that their contribution to a discharge, release or disposal of a hazardous waste can be distinguished;
- (2) the amount of hazardous substances involved;
- (3) the degree of toxicity or hazard of the materials involved;
- (4) the degree of involvement by parties in the generation, transportation, treatment, storage, or disposal of the substances;
- (5) the degree of care exercised by the parties with respect to the substances involved; and

- (6) the degree of cooperation of the parties with government officials to prevent any harm to public health or the environment.

Id. at 20–21. Wells’s report explained his application of these factors.

Wells further opined that Mallinckrodt was responsible for waste at SLAPS from 1946 to mid-1966 for a total of approximately 20.5 years. Although Wells conceded that Mallinckrodt did not officially operate SLAPS until 1953, he attributed responsibility to Mallinckrodt for the prior years because “it was always Mallinckrodt’s waste being stored at the site, being transported directly from Mallinckrodt’s downtown facility.” *Id.* at 21 n.45. Wells likewise attributed responsibility to Cotter for waste at Latty Avenue from mid-1966 through 1973, for a total of 7.5 years, notwithstanding that a subcontractor managed the site for the early part of this time period, from approximately mid-1966 to early 1967. Wells reasoned that, although Cotter contracted with the other entity, Cotter maintained responsibility for the materials.

James Clark

James Clark is a toxicologist trained in environmental health sciences, with extensive experience in evaluating the toxicological impacts of contaminants. *E.g.*, ECF No. 50-11, Defs.’ Ex. K, Clark Report as to Butler, at 1. Plaintiffs retained Clark to quantify the dose of radiation that each Plaintiff received from his or her exposure to the materials released by Defendants. Clark prepared a separate report with respect to each Plaintiff for this purpose.

In arriving at his opinions, Clark reviewed the U.S. Department of Health and Human Services Agency for Toxic Substances and Disease Registry (ATSDR) Public

Health Assessment Evaluation of Community Exposure Related to Coldwater Creek, St. Louis Airport/Hazelwood Interim Storage Site (HISS)/Futura Coatings NPL Site (ATSDR Report); Army Corps reports; discovery produced by Defendants; Plaintiffs' questionnaires produced to Defendants as part of Court-ordered early disclosures in this case; personal interviews with Plaintiffs; and a prior expert report prepared by Clark in connection with a related set of consolidated cases before the undersigned, *McClurg et al. v. Mallinckrodt, LLC, et al.*, 4:12-CV-00361-AGF. *Id.* at 4–5.

The ATSDR Report is a public health assessment prepared by the federal agency pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. § 9604(i)(6), in order to “evaluate[] potential exposures to people who played or lived near Coldwater Creek in North St. Louis County.” *See* ECF No. 50-3, Defs.’ Ex. C, at ii. The agency issued a draft report (Draft ATSDR Report) for public comment on June 18, 2018. *See* ECF No. 50-1, Defs.’ Ex. A. Following the public comment period, the ATSDR made several changes to the evaluation and issued a final report on April 30, 2019 (Final ATSDR Report). *See* ECF No. 50-3, Defs.’ Ex. C.

Clark’s reports, dated March 31, 2019, were prepared before the ATSDR issued its final report, and therefore relies on the Draft ATSDR Report. Clark examined the addresses at which each Plaintiff lived during the relevant period and the activities in which each Plaintiff engaged. He relied on the ATSDR’s assumptions regarding the average length of time individuals spent engaging in various activities in or around Coldwater Creek, as well as the amount of soil, sediment, or surface water an individual could ingest while living or playing near the creek. Then, Clark stated that “[us]ing the

method outlined in the [Draft ATSDR Report], it is possible to calculate the dose in millirems (mRem) that [each Plaintiff] received from exposure to radioisotopes deposited in Coldwater Creek and the adjacent areas.” ECF No. 50-11, Defs.’ Ex. K, Clark Report as to Butler, at 1.

Specifically, Clark used the exposure assessment formulas set forth in the Draft ATSDR Report in order to calculate each Plaintiff’s dose and risk. Clark’s report sets forth his calculations with respect to each Plaintiff’s intake and dose of radionuclides. In arriving at these calculations, Clark stated: “In order to provide a representative exposure point concentration describing the highest levels of contaminant [each Plaintiff] was exposed to over time while playing in the Coldwater Creek area, in particular to the concentrations of radionuclides described by ATSDR near [the Plaintiff’s residence], a reasonable maximum exposure [RME] approach was utilized.” *E.g.*, ECF No. 50-13, Defs.’ Ex. M, Clark Report as to Koterba, at 14. Clark described the RME as the 95% upper confidence limit (UCL) of the average exposure expected to occur at a site. Clark explained that the RME was a “conservative estimate” and was “within the range of possible exposures but higher than the ‘typical’ or average exposure.” *Id.*

Clark proceeded to set forth tables listing the exposure point concentrations for soil and sediment, noting the “minimum or background,” “maximum,” and 95% UCL levels for thorium-230, radium-226, and uranium-238 based on samples tested. *See id.* at 15. Clark then indicated that “[c]onsistent with the methodology from ATSDR, the highest UCL for each radionuclide was assumed to represent the exposure concentration for [each Plaintiff].” *Id.* at 15.

In addition to the RME, Clark calculated a “maximum” dose for each Plaintiff based on the highest recorded measurements of thorium-230, radium-226 and uranium-238 in data points sampled in the area. *See, e.g.*, ECF No. 50-13, Defs.’ Ex. M, Clark Report as to Koterba, App’x C3. Clark did not use the “maximum” dose calculations to arrive at his opinions, instead determining that the RME was the more reliable estimation. However, as discussed below, Hu relied on Clark’s maximum doses in his supplemental report regarding specific causation.

Clark also opined that the applicable natural background level of radiation ranged from approximately 0.9 to 55 millirem over the entire exposure period for each Plaintiff. *See* ECF Nos. 50-11 at Appendix C2; 50-12 at Appendix C2; 50-13 at Appendix C2; 50-14 at Appendix C2. Based on these numbers, Clark then opined that each Plaintiff was exposed to radionuclide levels several times higher than the background levels, and that each received an internal dose during his or her youth that was sufficiently high to increase the risk for developing cancer in multiple organs. *See* ECF Nos. 50-11 at 36; 50-12 at 38; 50-13 at 35; 50-14 at 35.

The Final ATSDR Report summarizes the changes made in response to public comments,⁶ including adding language to clarify that “ATSDR used conservative assumptions to account for a lack of historical data describing past contamination levels in residential areas near Coldwater Creek” and that “[a]ctual past exposures will never be known with certainty and could have been lower or higher than estimated in this report.”

⁶ Some of the changes were made in response to extensive public comments by Mallinckrodt’s expert, RAC. *See* ECF No. 50-3, Defs.’ Ex. C, at F-36 to F-65.

ECF No. 50-3, Defs.’ Ex. C. at 3. The Final ATSDR Report provided more detailed explanation of the public comments and changes in an appendix to the report. *Id.*

This appendix explicitly noted that the ATSDR’s evaluation adopted a “conservative approach” designed to protect “all exposed community members” from a public health perspective, and that the evaluation therefore had an “inherent inability to predict individual exposure and risk.” *Id.* at F-15. Likewise, the appendix noted that the report “cannot say whether or not an individual’s illness was caused by exposure to contaminants from Coldwater Creek”; that the report’s “estimated exposures do not necessarily apply to individuals or even an average individual”; and that the report “bases its conclusions on lifetime risks from [an] entire 33 years of exposure . . . [such that] our methodology would be a reasonable approximation for estimating lifetime risks” but “would not be used in a detailed dose reconstruction.” *Id.* at F-21, F-37, F-40.

Notably, contrary to Clark’s opinions, the Draft and Final ATSDR Reports did not find an elevated risk of cancer to the breast, brain, or mantle cell lymphoma—the sites of Plaintiffs’ cancers here. Rather, the Reports found such elevated risk only with respect to lung, bone, and skin cancer, and leukemia. *See* ECF No. 50-3, Defs.’ Ex. C, at 20–30.

In deposition testimony in this case and related litigation, Clark acknowledged that it would be inappropriate to use the ATSDR methodology on its own to calculate a particular individual’s dose. However, Clark testified that the methodology could be used to calculate an individual’s dose if the methodology were tailored to information specific to that individual. *See* ECF No. 50-4, Defs.’ Ex. D, Clark dep. in *Czapla v. Republic Services Inc.*, No. 18SL-CC00803-01 (Cir. Ct. St. Louis Cty. Aug. 19, 2020), at

33:5–34:16. Clark conceded that the ATSDR did not indicate that it would be appropriate to calculate an individual’s dose by attempting to individualize the ATSDR’s methodology, but Clark noted that the agency did not explicitly caution against such an approach. *Id.* at 34:6–16. Clark could not recall anyone in his field calculating individual dose in the way he did, but Clark believed that his approach fit within the paradigm of public health assessments generally. *See* ECF No. 50-2, Clark dep. at 255:17–256:7.

In his deposition, Clark also testified that, in arriving at his conclusions regarding exposure and dose, he relied on the ATSDR’s assumptions regarding the average time spent doing various recreational activities, rather than attempting to particularize this information based on each Plaintiff’s interviews, questionnaire responses, or deposition testimony. For example, Clark assumed that all Plaintiffs spent on average 2 hours per day for 96 days per year playing in or near Coldwater Creek, regardless of what he or she testified to in deposition. However, Clark adjusted the overall time period of exposure by looking to the actual years in which each Plaintiff lived or recreated near the relevant sites. *See generally, id.* at 182–187, 191–195.

Clark also testified regarding his calculation of the natural background level. He conceded that the ATSDR report assumed that the average natural background level of radiation in the United States was 360 millirem per year. *See id.* at 151:25–153:21; 175:19–24; 216:6–11. Clark testified that he calculated lower natural background levels—0.9 to 55 millirem over the entire exposure period—from data reported by the Argon National Laboratory and another institution “as their description of what the

naturally occurring concentrations would be in the area.” *Id.* at 123:16–124:3. Clark explained that he calculated the natural background levels in this way because he wanted to do an “apples-to-apples comparison,” meaning what each Plaintiff “would . . . have received if not for the presence of the radiation that was placed at SLAPS or at [Latty Avenue] or in the creek or in the sediment or through the community.” *Id.* at 124:4–125:8. Clark acknowledged that he was not aware of anyone else in the industry or in the relevant literature using his definition of background radiation. *Id.* at 217:22–218:14.

Howard Hu (Opinions Regarding Causation)

Howard Hu is a physician who is board certified in internal and occupational medicine, with advanced degrees in public health and epidemiology. In connection with his public health and epidemiology degrees, Hu took coursework in radiobiology, radiological protection, radiation epidemiology, and cancer epidemiology. He also served as Chair of the Research Commission for the International Physicians for the Prevention of Nuclear War, in which he co-authored articles and books on radiation and radiological and non-radiological hazards related to the production of plutonium.

Plaintiffs retained Hu to opine on general and specific causation.⁷ In connection with his report, Hu reviewed each Plaintiff’s medical records, responses to a family

⁷ The Court uses the term “general causation” to refer to the question of whether exposure to radiation can cause the types of cancer at issue here, and the term “specific causation” to refer to the question of whether exposure to radiation actually caused each Plaintiff’s cancer. *See In re Bair Hugger Forced Air Warming Devices Prod. Liab. Litig.*, 9 F.4th 768, 799 (8th Cir. 2021) (using those terms similarly).

history questionnaire on cancer, Clark's expert report, and the Draft ATSDR Report on which Clark relied. However, Hu did not examine or interview any of the Plaintiffs.

As to general causation, Hu opined that ionizing radiation can cause the four types of cancer suffered by Plaintiffs: breast cancer, brain cancer or brain tumor, and mantle cell lymphoma. As to specific causation, Hu opined that each Plaintiff's exposure to thorium-230, radium-226, and uranium-238 from Coldwater Creek did in fact more likely than not cause or contribute toward the development of his or her cancer. Hu disclosed a separate report with respect to each of the four Plaintiffs.

In order to support his specific causation opinions, Hu relied on Clark's RME for each Plaintiff with respect to the specific organ that was the site of each Plaintiff's cancer, and compared that to the natural background radiation calculated by Clark. For example, as to Koterba, Hu took Clark's calculation of RME to Koterba's brain (the site of his tumor), 5.77 to 16.3 millirem, and Clark's estimation that this dose was 4.8 to 6 times the estimated dose from natural background radiation, which Clark calculated to be 1.2 to 2.7 millirem. ECF No. 52-3, Defs.' Ex. A-3, at 6; *see also* ECF No. 50-13, Defs.' Ex. M, at 31, Appendix C2.

Hu concluded from Clark's calculations that each Plaintiff had exposure of thorium-230, radium-226, and uranium-238 to the organ in which his or her cancer developed at levels several times more than the natural background level; that these exposures occurred during childhood, which is known to be an age at which individuals are more susceptible to carcinogenic exposures; and that each Plaintiff's family history

questionnaires and medical records did not indicate other risk factors for the cancer, such as immediate family history or certain genetic disorders.

On September 30, 2019, Hu disclosed a supplement to each report. In the supplemental reports, Hu stated that instead of relying on Clark's RME for the specific organ at issue, he would rely on a different value in Clark's report for organ dose, namely, the "maximum" dose calculated by Clark, which was several times the amount of the RME. For example, whereas the RME for exposure to Koterba's brain was calculated by Clark to be 5.77 to 16.3 millirem, the "maximum" exposure to Koterba's brain as calculated by Clark ranged from 45.2 to 272 millirem. *See* ECF No. 52-16, Defs.' Ex. K3 at 1.

Hu stated that the updated opinions in the supplemental reports were based on his review of the materials and the Plaintiffs' deposition transcripts. Hu opined that each Plaintiff's total duration of exposure and the conservative nature of Clark's estimates suggested that each Plaintiff's exposure was in fact closer to the "maximum" exposure rather than the RME. *See, e.g., id.* at 2.

In his deposition in this case, Hu admitted that he relied on Clark's reports for exposure numbers, that he understood that his "opinions are only as good as [Clark's] numbers," and that he did not attempt to validate Clark's calculations for organ doses or natural background radiation levels. Hu further conceded that the 360 millirem per year natural background level referenced in the ATSDR report is the commonly used metric for natural background but that Clark did not use that number in his calculation of natural background level. *See* ECF No. 52-5, Defs.' Ex. B, Hu dep. at 95–97; 119-20. Hu

admitted that he did not know of anyone else to use the term “natural background radiation” in the way that Clark did. *Id.* at 110:1–16.

Hu also acknowledged in his deposition and his supplemental reports that at least two of the Plaintiffs had a significant history of smoking. Hu stated that he did not discuss these Plaintiffs’ histories of smoking in their respective reports because he did not believe smoking to be a significant risk factor for their particular types of cancer. *Id.* at 219, 224, 228; *see also* ECF Nos. 52-16 & 52-17, Defs.’ Exs. K3 & K4.

DISCUSSION

The admission of expert testimony in federal court is governed by Federal Rule of Evidence 702. *Wagner v. Hesston Corp.*, 450 F.3d 756, 758 (8th Cir. 2006). Rule 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The rule was amended in 2000 in response to *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), which charged trial judges with a “gatekeeping” role to exclude unhelpful and unreliable expert testimony. As the proponent of the expert testimony in question, Plaintiffs have the burden to prove its admissibility by a preponderance of the evidence. *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th

Cir. 2001).

“Rule 702’s ‘screening requirement’ has been boiled down to a three-part test.” *Bair Hugger*, 9 F.4th at 777 (citation omitted). “First, the testimony must be useful to the finder of fact in deciding the ultimate issue of fact, meaning it must be relevant. Second, the expert must be qualified to assist the finder of fact. Third, the testimony must be reliable or trustworthy in an evidentiary sense.” *Id.* (citations omitted).

With respect to the third requirement, which is the focus of Defendants’ motions, “[t]he standard for judging the evidentiary reliability of expert evidence is lower than the merits standard of correctness.” *See Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 625 (8th Cir. 2012) (citation omitted). Factors relevant to the reliability and relevancy determinations include: “(1) whether the theory or technique can be or has been tested; (2) whether the theory or technique has been subjected to peer review or publication; (3) whether the theory or technique has a known or potential error rate and standards controlling the technique’s operation; and (4) whether the theory or technique is generally accepted in the scientific community.” *Russell v. Whirlpool Corp.*, 702 F.3d 450, 456 (8th Cir. 2012). Additional factors include “whether the expertise was developed for litigation or naturally flowed from the expert’s research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case.” *Lauzon v. Senco Prod., Inc.*, 270 F.3d 681, 687 (8th Cir. 2001). These factors “should only be relied upon to the extent that they are relevant and the district court must customize its inquiry to fit the facts of each

particular case.” *Shuck v. CNH Am., LLC*, 498 F.3d 868, 874 (8th Cir. 2007).

Although “the focus of the reliability inquiry ‘must be solely on principles and methodology, not on the conclusions that they generate, . . . conclusions and methodology are not entirely distinct from one another.’” *Bair Hugger*, 9 F.4th at 777 (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). In particular, “a district court may exclude expert testimony if it finds that there is simply too great an analytical gap between the data and the opinion proffered, . . . [or] if it is so fundamentally unsupported by its factual basis that it can offer no assistance to the jury.” *Id.* at 778 (internal citations omitted).

Proposed expert testimony “must be supported by appropriate validation—i.e., good grounds, based on what is known”; expert “knowledge connotes more than subjective belief or unsupported speculation.” *Daubert*, 509 U.S. at 590 (citation omitted). However, “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Olson v. Ford Motor Co.*, 481 F.3d 619, 626 (8th Cir. 2007). And any “doubts regarding whether an expert’s testimony will be useful should generally be resolved in favor of admissibility.” *Clark v. Heidrick*, 150 F.3d 912, 915 (8th Cir. 1998).

Wells (Opinions Regarding Defendants’ Releases)

Defendants seek to exclude Wells’s testimony in its entirety on the grounds that Wells is unqualified to render opinions regarding compliance with federal radiation safety standards and that his opinions are otherwise unhelpful and unreliable.

Specifically, Mallinckrodt argues that Wells's opinions regarding releases of radon-222 and thorium-230 at SLAPS in excess of the federal limit set forth in 10 C.F.R. § 20.106 (1960) are not based on annual average data, as required by the federal standard, and also rely on invalid factual assumptions. These factual assumptions include that the radon that may have existed in 1948 continued to exist in 1953, when Mallinckrodt began operating SLAPS, despite that the K-65 had been removed from SLAPS by that time; and that any thorium-230 that existed was soluble rather than insoluble.⁸

Likewise, both Defendants argue that Wells's supplemental opinion regarding Defendants' releases of contaminated soil and sediment in excess of the applicable federal limit fails to follow proper methodology for determining compliance with the federal standard.

Further, Cotter adds that Wells's opinions regarding its releases of all radionuclides at the Latty Avenue site should be excluded because the opinions are fundamentally unsupported for reasons explained by Cotter's expert; because the opinions are based on air modeling, a subject in which Wells is not qualified as an expert; and because Wells did not perform any modeling himself but instead incorrectly relied on Mallinckrodt's expert's models without validation.

Finally, both Mallinckrodt and Cotter further argue that Wells's allocation opinion is unreliable because it excludes all other sources of radiation exposure, relies on false factual assumptions, and is litigation-driven rather than based in science.

⁸ The applicable federal limit for soluble thorium was lower than the limit for insoluble thorium.

I. Releases in Excess of Federal Limits

a. Releases from SLAPS and Coldwater Creek

The Court agrees with Defendants that exclusion is warranted with respect to Wells's opinions that the concentrations of radon-220 and thorium-230 at the boundary of SLAPS, the site operated by Mallinckrodt, and other unspecified radionuclides in soil and sediment in and around Coldwater Creek, all exceeded the federal limits set forth in 10 C.F.R. § 20.106 (1960). Section 20.106 prohibits a licensee from “possess[ing], us[ing] or transfer[ring] licensed material in such a manner as to release into air or water in any unrestricted area any concentration of radioactive material in excess of limits specified in Appendix B, Table II, of this part.” 10 C.F.R. § 20.106(b) (1960), 25 Fed. Reg. 8595, 8599 (Sept. 7, 1960). The regulation further states that “determinations as to the concentration of radioactive material shall be made with respect to the point where such material leaves the restricted area.” *Id.* § 20.106(c).

The regulation explicitly states that, for the purpose of the paragraph restricting releases in excess of the specified limits, “concentrations may be averaged over periods not greater than one year.” *Id.* § 20.106(b). As the Third Circuit held in *McMunn*, discussed above, plaintiffs seeking to prove a breach of § 20.106 are “required to show a breach using annual averaging.”⁹ *McMunn.*, 869 F.3d at 267 (3d Cir. 2017). “[D]ata relating to individual moments in time fails to show a breach.” *Id.*

⁹ Notably, the Third Circuit maintained that annual averaging was the requirement to show a breach of the federal standard regardless of whether the defendants kept proper records regarding contamination levels. *See McMunn*, 869 F.3d at 268, 268 n.23.

This Court agrees with the Third Circuit that the use of the word “may” in the phrase “concentrations may be averaged over a period not greater than one year” gives the AEC discretion to determine whether to average annually, but it does not give tort plaintiffs that power. *See id.* (reasoning that “[g]iving tort plaintiffs the power to determine retroactively the period over which a violation is assessed would allow them to fix the standard case by case and plant by plant” and would render the standard of care “elusive and undeterminable”).

Plaintiffs argue that § 20.106 does not in fact apply to Mallinckrodt because Mallinckrodt was not acting as a licensee or because the materials at issue were not federally regulated at the relevant time. However, that argument is not properly before the Court at this stage. Plaintiffs’ expert rendered opinions that the concentrations of radon-220 and thorium-230 at the boundary of SLAPS exceeded the federal limits set forth in 10 C.F.R. § 20.106. The question before the Court at this stage is whether these opinions are reliable.

Wells admittedly based his opinions regarding breach of the federal standards on samples taken from individual moments in time, rather than annual averages. With respect to radon-222, Wells relied on single measurement taken in 1948. As to thorium-230, Wells relied on the highest measurement from a set of samples taken as part of Mallinckrodt’s annual reporting.¹⁰ And regarding the contaminated soil and sediment in

¹⁰ Although Mallinckrodt’s annual report also listed averages of the samples taken, Wells did not rely on those averages and instead relied only on the highest recorded measurement.

Coldwater Creek and its tributaries, addressed in Wells's supplemental report, Wells does not even identify a radionuclide or any applicable federal limit before concluding that the limitations set forth in the federal regulations were breached. Wells's failure to use annual average releases renders his opinions regarding concentrations at SLAPS and Coldwater Creek and its tributaries in excess of the limits § 20.106 unreliable.

For all of these reasons, the Court will exclude Wells's opinions that concentrations of contaminants at SLAPS and Coldwater Creek exceeded the federal limit set forth in 10 C.F.R. § 20.106 (1960), without reaching Defendants' other arguments in support of such exclusion.

b. Releases from Latty Avenue

The Court will likewise exclude Wells's opinions that the concentrations of radon-220 and thorium-230 at the boundary of Latty Avenue, the site operated by Cotter, exceeded the federal limits set forth in 10 C.F.R. § 20.106 (1960). With respect to excess radon releases, the Court agrees with Cotter that Wells's reliance on the RAC's radon measurements for SLAPS as a proxy for Latty Avenue was fundamentally unsupported. Plaintiffs do not dispute that the RAC's radon measurements with respect to SLAPS related to radon emissions from K-65 drums and that K-65 was never present at Latty Avenue. Wells has offered no explanation or scientifically sound basis for applying the RAC's K-65-based radon measurements for SLAPS to Latty Avenue. Thus, "there is simply too great an analytical gap between the data and the opinion offered." *See Bair Hugger*, 9 F.4th at 778.

As to excess thorium-230 releases, Wells based his opinion regarding breach of the federal standard on concentrations for individual quarters between 1968 and 1971 and only when the dryer was operating, rather than calculating annual average concentrations. As noted above with respect to SLAPS, the Court concludes that any opinion regarding a breach of § 20.106 requires showing a breach using annual averaging. *See McMunn*, 869 F.3d at 267. Moreover, Plaintiffs do not dispute Cotter's expert's assertion that "had Dr. Wells calculated annual average concentrations (either on a calendar or operational year basis), these concentrations would have been significantly less than the quarterly numbers he provides in Table 3 of his report." ECF No. 54-1, Cotter's Ex. A, at 24. In short, Wells's opinion that Cotter released thorium-230 in excess of the federal standard is fundamentally unsupported. *See Bair Hugger*, 9 F.4th at 778.

For these reasons, the Court will exclude Wells's opinions that concentrations of contaminants at Latty Avenue exceeded the federal limit set forth in 10 C.F.R. § 20.106 (1960), without reaching Defendants' other arguments in support of such exclusion.¹¹

II. Allocation

Unlike his opinions regarding excess releases, Wells's opinion regarding allocation does not suffer from the same reliability problems. Rather, the Court agrees with Plaintiffs that Defendants' attacks on Wells's allocation opinion are focused on the

¹¹ The Court expresses no opinion regarding whether the AEC's notices of non-compliance for Latty Avenue, referenced in Wells's report, may constitute independent proof of breach of the federal standard. Aside from referencing the existence of the notices, Wells does not appear to rely on the notices or information contained therein in connection with his calculations of excess contamination.

facts underlying those opinions. Such factual challenges are better explored on cross-examination. Although the Gore factors Wells relied upon in arriving at his allocation opinion are based on CERCLA rather than the PAA, nothing in these statutes, the caselaw, or the record suggests that the Gore factors are inherently irrelevant to allocation of responsibility under the PAA or that the allocation opinion is so fundamentally unsupported as to warrant exclusion.

III. Wells's Qualifications

After excluding Wells's opinions regarding the specific issue of Defendants' compliance with federal radiation safety standards, the Court finds Wells well qualified to offer his remaining opinions about the existence of contamination generally at the relevant sites, the pathways through which the contamination spread, and the allocation of responsibility as between Mallinckrodt and Cotter. Therefore, the Court will not exclude those remaining opinions.

Clark (Opinions Regarding Plaintiffs' Doses)

Defendants seek to exclude Clark's testimony in entirety because he is not qualified to testify as an expert in radiation dosimetry and because his opinions are unreliable and unhelpful. Specifically, Defendants argue that Clark's use of the Draft ATSDR Report to opine on Plaintiffs' individual doses contradicts the Report's explicit disclaimer cautioning against such use and also fails to take into account changes made to the Final Report; that Clark improperly relied on the ATSDR's uniform assumptions regarding the types of activities individuals engaged in and length of time engaged in such activities, rather than on Plaintiffs' deposition testimony and other evidence of

Plaintiffs’ actual experiences; that Clark’s dose calculations were created for litigation, cannot be reproduced or tested, and according to Mallinckrodt’s expert, carry an 83% error rate; and that Clark’s calculation of the natural background level of radiation is contrary to the industry standard and unsupported by the relevant literature. Further, Defendants argue that Clark’s “maximum” dose calculations, which were primarily used by Hu in his supplemental reports, are based on an impossible factual scenario.

The Court agrees with Defendants that the methodology employed and conclusions drawn by the ATSDR do not easily translate to reliable proof of Plaintiffs’ individual doses here. *See Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001) (holding that because “[t]he methodology employed by a government agency results from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances,” an FDA decision that a particular drug could cause strokes was “unreliable proof of medical causation,” and noting that “the FDA employs a reduced standard (vis-a-vis tort liability) for gauging causation when it decides to rescind drug approval”). The Final ATSDR Report made that clear through its disclaimers, specifically cautioning that its public-health driven, simplified approach would “not be used in a detailed dose reconstruction.” ECF No. 50-3, Defs.’ Ex. C, at F-11. Clark also admitted as much in his deposition testimony.

It may be possible to “bridge the gap” between the ATSDR’s conservative, regulatory conclusions regarding potential exposures and the causation-related inquiry here regarding Plaintiffs’ actual exposures and doses. *See Bair Hugger*, 9 F.4th at 779–80 (“So long as an expert does the work to bridge the gap between association and

causation, a study disclaiming having proven causation may nevertheless support such a conclusion.”) (citation omitted). Clark suggested that the gap could be bridged by tailoring the ATSDR’s methodology to information specific to each individual.

However, aside from adjusting for the number of years each Plaintiff lived in the area, Clark did not tailor the ATSDR’s methodology. He instead relied on the ATSDR’s admittedly conservative assumptions regarding the risk of exposure. For example, as noted above, Clark assumed that all Plaintiffs spent on average 2 hours per day for 96 days per year playing in or near Coldwater Creek, even though he conceded that Butler testified that she had spent much less time near the creek. *See* ECF No. 50-2, Clark dep. at 182:4–184:1.

Plaintiffs contend that Clark’s assumptions regarding “the total time each Plaintiff spent at contaminated areas and activities they engaged in there are questions of fact for the jury.” ECF No. 69 at 13. Plaintiffs’ point may have been well taken if Clark had attempted to calculate each Plaintiff’s activities and duration at the sites—which information was admittedly available to Clark by way of deposition testimony, questionnaire responses, and Clark’s own interviews with Plaintiffs—and if Defendants merely disputed the veracity of Clark’s assumptions. But Clark made no such attempt. Rather, he relied on the ATSDR’s conservative assumptions without tailoring the methodology to each Plaintiff. *See McMunn*, 869 F.3d at 272 (holding an expert opinion regarding causation of cancer by exposure to uranium “requires more than an assumption about the effect of living within a mile of the [nuclear facility at issue]”).

Plaintiffs also argue that the ATSDR’s methodology to arrive at a “reasonable approximation for estimating lifetime risks” was properly tested and generally accepted in the applicable scientific community. However, Clark’s application of that methodology to calculate a detailed dose reconstruction for individuals, contrary to the advice of ATSDR, does not have the same support, validation, or general acceptance. It was instead created for this litigation.

More importantly, in order to opine that each Plaintiff was exposed to radionuclide levels several times higher than background levels, Clark did not use the ATSDR’s natural background number of 360 millirem *per year*, which is the standard in this field. *See also In re TMI Litig.*, 193 F.3d 613, 644 n.50 (3d Cir. 1999), *amended*, 199 F.3d 158 (3d Cir. 2000) (noting that, while “[n]atural background radiation levels vary widely throughout the world . . . it has been estimated that the average annual dose in the United States from natural background radiation is . . . around 3 mSv or 300 mrems”); *McMunn*, 869 F.3d at 279 (McKee, J., concurring) (“[T]he typical average individual exposure in the United States from natural background sources is about 300 millirems per year.”) (citing U.S. Nuclear Regulatory Comm’n, *Background radiation*, <https://www.nrc.gov/reading-rm/basicref/glossary/background-radiation.html>). Had he done so, he would have found that each Plaintiff’s exposure was in fact lower than the background level.

Rather, Clark created his own background numbers, which ranged from approximately 0.9 to 55 millirem *over the entire exposure period for each Plaintiff*. Clark has not offered a scientifically sound reason for doing so. Nor has his method of

calculating the natural background level of radiation been tested, subjected to peer review, or shown to be generally accepted in the scientific community. Clark's methodology in this respect, like his methodology for calculating the individual doses, was created for litigation without relevant scientific support.¹² *Cf. Bair Hugger*, 9 F.4th at 783 (holding that the scientific reliability of expert testimony "developed for litigation" can be "shown by proof that the research and analysis supporting the proffered conclusions have been subjected to normal scientific scrutiny through peer review and publication"). Clark's invented methodology allowed him to find an elevated risk of breast cancer, brain cancer, and mantle cell lymphoma where the ATSDR did not, even though some of the Plaintiffs lived near the sites for much less than the ATSDR's assumed 33 years.

Plaintiffs contend that they do "not need to produce a mathematically precise table equating levels of exposure with levels of harm" in order to show that Plaintiffs were exposed to a toxic level of the substances at issue. ECF No. 69 at 18 (citing *Bonner v. ISP Technologies, Inc.*, 259 F.3d 924, 928 (8th Cir. 2001)).¹³ Again, that question is not

¹² Clark's lack of education, training, or experience in the specific area of radiation dosimetry or closely related fields compounds this problem.

¹³ *Bonner* involved a new toxic tort claim regarding the organic solvent FoamFlush. *Bonner*, 259 F.3d at 928. Noting that the relationship between the solvent and the plaintiff's injury had not been studied by experts, the Eighth Circuit held that "[t]he first several victims of a new toxic tort should not be barred from having their day in court simply because the medical literature, which will eventually show the connection between the victims' condition and the toxic substance, has not yet been completed." *Id.* It is not at all clear that the Eighth Circuit would come to the same conclusions with respect to a more well studied toxin, such as radiation.

properly before the Court at this stage. Plaintiffs' expert has opined that such levels of exposure can be calculated and has purported to perform such calculations. The question before the Court now is whether his calculations are sufficiently reliable. For the reasons stated above, the Court concludes that they are not. Therefore, the Court will exclude Clark's opinions without reaching Defendants' other arguments in support of such exclusion.

Hu (Opinions Regarding Causation)

Defendants seek to exclude Hu's testimony in entirety because Hu, who is not an oncologist or radiation specialist, is not qualified to opine on specific causation here, and because Hu's opinions are not reliable or relevant. In particular, Defendants argue that Hu's opinions regarding specific causation in both his original and supplemental reports depend on Clark's dose and exposure opinions, which are unreliable for the reasons stated above, and because Hu failed to rule out alternative causes. Defendants also argue that Hu's supplemental opinions should be excluded as untimely.

I. General Causation

Defendants do not challenge Hu's general causation opinions that ionizing radiation can potentially cause the cancers at issue here, namely, cancer to the breast or brain, or mantle cell lymphoma. Indeed, Defendants do not dispute the general proposition that excessive exposure to radiation can cause various types of cancer. Hu's general causation opinions are not so fundamentally unsupported as to warrant exclusion, and the Court concludes that Hu's discussion of the particular types of cancer at issue here would be helpful to a jury in assessing general causation. The Court further

concludes that Hu's advanced education and experience in medicine, public health, and epidemiology, which includes specific education and experience in radiation epidemiology and cancer epidemiology, also qualify him to render such general causation opinions.

II. Specific Causation

The Court reaches a different conclusion with respect to Hu's specific causation opinions, that each Plaintiff's exposure to thorium-230, radium-226, and uranium-238 from Coldwater Creek more likely than not caused or contributed toward the development of his or her cancer. Those opinions admittedly depend on Clark's calculations regarding each Plaintiff's dose and exposure to the radionuclides in excess of natural background levels.

Hu did not validate or test Clark's calculations, instead relying on Clark to do so. Hu admitted that his opinions were only as good as Clark's numbers. Hu also acknowledged that Clark used a natural background number that was a small fraction of the number commonly used in this field. The Court has found that Clark's methodology was unreliable. Hu's derivative causation opinions fail for the same reasons, at least to the extent they assert that radiation caused or contributed to the Plaintiffs' cancers. And Hu's use of Clark's "maximum" doses in his supplemental reports, when Clark himself did not use such inflated numbers and without scientific justification for doing so, is likewise unreliable.

Plaintiffs argue that Hu's specific causation opinions are reliable because Hu performed a differential etiology. "In performing a differential diagnosis, a physician

begins by ‘ruling in’ all scientifically plausible causes of the plaintiff’s injury. The physician then ‘rules out’ the least plausible causes of injury until the most likely cause remains. The final result of a differential diagnosis is the expert’s conclusion that a defendant’s product caused (or did not cause) the plaintiff’s injury.” *Glastetter*, 252 F.3d at 989. But Hu admittedly relied on Clark’s dosage calculations to “rule in” radiation exposure at a sufficient level to plausibly cause Plaintiffs’ injuries. Aside from Clark’s (unreliable) calculations, Hu does not cite to any evidence supporting his finding that each Plaintiff was exposed to radiation at a level sufficient to cause his or her particular cancer. For these reasons, the Court will exclude Hu’s specific causation opinions that radiation caused or contributed to Plaintiffs’ cancers without reaching Defendants’ alternative arguments for such exclusion.

However, Hu may be permitted to testify regarding those portions of his specific causation opinions that “rule out” other causes of Plaintiffs’ cancers, such as family history, to the extent Plaintiffs wish to introduce such testimony. Hu based the portions of his opinions ruling out alternative causes on his review of Plaintiffs’ medical records and family history questionnaires. Defendants’ challenges to Hu’s attempts to rule out other potential causes are primarily challenges to Hu’s factual assumptions. Such challenges are better explored on cross examination.

After excluding the portion of Hu’s opinions ruling in radiation as a cause of Plaintiffs’ cancers and the resulting opinions as to specific causation, the Court finds that Hu’s opinions that “rule out” alternative causes of Plaintiffs’ cancers are not so fundamentally unsupported as to warrant exclusion. This, of course, assumes Plaintiffs

can establish the relevance of such testimony “ruling out” causes if there is no evidence “ruling in” radiation as a cause.

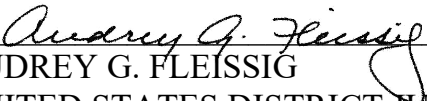
CONCLUSION

Accordingly,

IT IS HEREBY ORDERED that Defendants’ joint motion to exclude the testimony of James Wells, Ph.D., is **GRANTED in part and DENIED in part**, as set forth above. ECF No. 47.

IT IS FURTHER ORDERED that Defendants’ joint motion to exclude the testimony of James Clark, Ph.D., is **GRANTED**. ECF No. 49.

IT IS FURTHER ORDERED that Defendants’ joint motion to exclude the testimony of Howard Hu, M.D., is **GRANTED in part and DENIED in part**, as set forth above. ECF No. 51.



AUDREY G. FLEISSIG
UNITED STATES DISTRICT JUDGE

Dated this 31st day of March, 2022.